AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING
CONFERENCE CALL
July 29, 2016
12:00 pm

Call-in number: 888-670-3525
Code: 5134896685

Board Members
Debra B. Glass, BPharm, Chair, Tallahassee
Mark Mikhael, PharmD, Vice-Chair, Orlando
Goar Alvarez, PharmD, Cooper City
Michele Weizer, PharmD, Boca Raton
Leo "Lee" Fallon, BPharm, PhD, The Villages
Gavin Meshad, Consumer Member, Sarasota
Jeenu Philip, BPharm, Jacksonville
Jeffrey J. Mesaros, PharmD, JD, Orlando
David Bisaillon, Consumer Member, Bradenton

Board Staff
Allison Dudley, Executive Director
Amber Wilkins, Regulatory Specialist III

Board Counsel
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

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1. Rule 64B16-32.001, F.A.C. Nonresident Pharmacy Permit
2. Rule 64B16-32.007, F.A.C. Nonresident Sterile Compounding Permit for Nonresident Pharmacies
3. Rule 64B16-32.009, F.A.C. Nonresident Sterile Compounding Permit for an Outsourcing Facility

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-32.001 Nonresident Pharmacy Permit.
PURPOSE AND EFFECT: The Board proposes the rule promulgation to create a rule concerning how to obtain a nonresident pharmacy permit, to update and streamline the process for efficiency, and to incorporate the Nonresident Pharmacy Permit Application.
SUMMARY: The rule promulgation will create a rule concerning obtaining a nonresident pharmacy permit, update and streamline the process for efficiency, and incorporate the Nonresident Pharmacy Permit Application.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.005, 465.0156 FS.
LAW IMPLEMENTED: 465.0156, 456.065 (3) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allison Dudley, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-32.001 Nonresident Pharmacy Permit.
This permit is required before a pharmacy that is located outside the geographical boundaries of Florida can ship, mail, or deliver, in any manner, a dispensed medicinal drug into Florida.

(1) This permit does not authorize the nonresident pharmacy to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida.

(2) An applicant for a nonresident pharmacy permit shall submit an application using Form DH-MQA 1217 (eff. 04/16), "Nonresident Pharmacy Permit Application," which is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref- or http://floridapharmacy.gov. Applicants for a nonresident pharmacy permit must comply with all requirements in section 465.0156, F.S.

Rulemaking Authority 465.005, 465.0156 FS. Law Implemented 465.0156, 456.065 (3) FS. History – New .

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 5, 2016
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 9, 2016

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

NONRESIDENT PHARMACY PERMIT APPLICATION

July 2016

DH-MQA 1217, 07/16
Rule 64B16-32.001

Nonresident Pharmacy Permit Application Information

Nonresident Pharmacy Registration as authorized by Section 465.0156, F.S., is required for those pharmacies located outside the state and which ships, mails, or delivers a dispensed medicinal drug into this state. In order to dispense medicinal drugs into Florida, the pharmacy and the pharmacist designated as the prescription department manager or equivalent must be licensed in the state of location. This permit does not authorize the nonresident pharmacy to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida.

The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of $255.00. The application must have the original signature of the owner or officer of the establishment. You must provide a toll free number, which is available 6 days a week, not less than 40 hours, and the pharmacist must be able to access the patient records.

Definition:

For purposes of this application, when the term “affiliated person” is used, the term shall mean any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy.

Application Processing: **Please read all instructions before completing your application.**

1. Please mail the application and the $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

   Department of Health
   Board of Pharmacy
   P.O. Box 6330
   Tallahassee, Florida 32314-6320

   OR, use the following address if you are using express mail:

   Department of Health
   Board of Pharmacy
   4052 Bald Cypress Way, Bin C-04
   Tallahassee, FL 32399-3254

2. Please submit a letter of licensure verification for the facility and the prescription department manager or your state’s equivalent to a PDM (i.e., Pharmacist in Charge) from the state board of pharmacy where you are located. The letter must include:

   a. Original Licensure Date;
   b. Expiration Date; and
   c. Licensure Status.

3. Please submit a copy of your most recent inspection by the state board of pharmacy or the entity responsible for conducting inspections in the state where you are physically located.

Within 30 days of receipt of your application and fees, the board office will notify you regarding any missing documents and your application status. If your application is incomplete, you will be notified in writing of what is required to deem your application complete. An incomplete application will expire after one year.

FLORIDA BOARD OF PHARMACY
P.O. Box 6330
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
www.floridaspharmacy.gov

NONRESIDENT PHARMACY PERMIT APPLICATION

Please submit the application fee and unlicensed activity fee totaling $255 with your application.

List Federal Employer Identification Number:

1. Corporate Name	Telephone Number
2. Doing Business As (d/b/a)	**E-Mail Address (optional)**

3. Mailing Address

City	State	Zip

4. Physical Address

City	State	Zip

5. List Prescription Department Manager (PDM) or equivalent

Name	License No.	Start Date

6. Contact Person	Telephone Number
7. DEA Registration Number	**8. Do you have 24 hour access to patient records?**
	____YES ____NO If no explain on separate sheet
9. Operating Hours	**10. Provide the Toll-Free Telephone number available six days a week for 40 hours below:**

11. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE SECRETARY OF STATE'S OFFICE WHERE THE PHARMACY IS LOCATED.

b. List each principal, officer, agent, managing employee or affiliated person of the applicant.
Attach a separate sheet if necessary.

Name and Title	Date of Birth	Mailing Address	% of Ownership

Pursuant to Section 456.0635(2), *Florida Statutes*, questions 12 through 18 must be answered. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If "no", skip to 13.)

Yes _____ No _____

12a. If "yes" to 12, for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

12b. If "yes" to 12, for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction.

Yes _____ No _____

12c. If "yes" to 12, for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____

12d. If "yes" to 12, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).

Yes _____ No_____

13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", do not answer 14)

Yes _____ No _____

14. If "yes" to 13, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes _____ No _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If "no", do not answer 16.)

Yes _____ No _____

16. If "yes" to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or any other state Medicaid program? (If "no", do not answer 17a and 17b)

Yes _____ No _____

17a. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?

Yes _____ No _____

17b. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes_____ No_____

19. Has the principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to a crime other than a minor traffic offense?

Yes ____ No ____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

20. Is the applicant currently registered or permitted in any state? If yes, provide the jurisdiction, permit type, and permit number for each permit. ***Attach a separate sheet if necessary.***

Yes _____ No _____

State	Permit Type	Permit Number

21. Has the applicant or any principal, officer, agent, managing employee, or affiliated person ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. ***Attach a separate sheet if necessary.***

Yes _____ No _____(If yes, explain on a separate sheet providing accurate details)

Pharmacy Name	State	Status

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, any principal, officer, agent, managing employee, or affiliated person in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

23. Is there any other permit issued by the Florida Department of Health located at the physical location address on this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

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Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other item, in connection with an application for a license or permit, as set forth in Section 456.072(1)(h), F.S.

SIGNATURE _____ TITLE _____DATE_____

Owner/Officer

NONRESIDENT PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Faxed applications will not be accepted.

_____ **Application Completed (all questions answered)**

_____ **Application Signed**

_____ **Pharmacy Manager and Pharmacy License Verification from the resident state**

_____ **$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)**

_____ **Certificate of Status for the Corporation from the Secretary of State**

_____ **Copy of the most recent Pharmacy Inspection Report**

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-32.007 Nonresident Sterile Compounding Permit for Nonresident Pharmacies.
PURPOSE AND EFFECT: The Board proposes the rule promulgation to create a rule regarding nonresident sterile compounding permit for nonresident pharmacies and to incorporate the nonresident sterile compounding permit application for nonresident pharmacies.
SUMMARY: A rule will be created regarding nonresident sterile compounding permit for nonresident pharmacies and to incorporate the nonresident sterile compounding permit application for nonresident pharmacies.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.0158 FS.
LAW IMPLEMENTED: 465.0158, 456.065(3) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allison Dudley, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-32.007 Nonresident Sterile Compounding Permit for Nonresident Pharmacies
This permit is required before a nonresident pharmacy ships, mails, delivers, or dispenses, in any manner, a patient-specific compounded sterile product into Florida.

(1) A nonresident pharmacy that obtains a nonresident sterile compounding permit may only ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida.

(2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding Only.

(3) A nonresident pharmacy applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5003-MQA (eff. 04/16), "Nonresident Sterile Compounding Permit Application for Nonresident Pharmacies," which is hereby incorporated by reference. The Form is available at http://www.flrules.org/Gateway/reference.asp?No=Ref- or http://floridaspharmacy.gov. An applicant for this permit must comply with all provisions of section 465.0158, F.S.

Rulemaking Authority 456.0158, FS. Law Implemented 465.0158, 456.065(3) FS History New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 5, 2016
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 9, 2016

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR NONRESIDENT PHARMACIES

JULY 2016

DH5003-MQA, 07/16
Rule 64B16-32.007, F.A.C.

Nonresident Sterile Compounding Permit for Nonresident Pharmacies Information

A Nonresident Sterile Compounding Permit as authorized by Section 465.0158, *Florida Statutes* is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

Definition:

For purposes of this application, when the term "affiliated person" is used, the term shall mean any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy.

Application Processing

1. Please mail the application and the $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6330
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

2. Along with the application, Nonresident Pharmacies must submit the following:

a. A letter of licensure verification for both the facility and the Prescription Department Manager or Pharmacist in Charge or equivalent from the state, territory or district regulatory or licensing agency. The letter must include the original licensure date, the expiration date, and current licensure status.

b. A copy of a current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report is current if the inspection was conducted within six months before the date of submission of this application. The current inspection report must demonstrate that the applicant is fully compliant with chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted in Rule 64B16-27.797(1), Florida Administrative Code.

If you are unable to submit a current inspection report demonstrating compliance with the applicable chapters of the pharmacopeia, due to acceptable circumstances as established by Rule 64B16-28.905, F.A.C. or if no current inspection has been performed, the applicant may:

- Submit a current and satisfactory inspection report from an entity approved by the board. Approved entities can be found on the Board's website at www.floridaspharmacy.gov; or

- Request the Department to perform an onsite inspection in which all costs are borne by the applicant.

c. A copy of the applicant's existing policies and procedures for sterile compounding**.** The policies and procedures must comply with pharmaceutical standards in chapters 797, 71, 85 and 731 of the United States Pharmacopoeia.

d. Any and all other documentation requested or mandated within this application**.**

3. Once an application is complete and approved, the Department will issue a permit which you will receive within 7 days.

All pharmacies must answer the following questions. The questions will assist in the Board's review of your application to determine your pharmacy's compliance the applicable chapters of the United States Pharmacopeia. Please answer the following questions as completely and legibly as possible. Attach additional pages if needed.

1. These questions relate to your primary engineering controls.

a. How many primary engineering controls do you have? _____

b. What kind are they? (select all that apply)

☐ Laminar Airflow Workbench (LAFW)
☐ Compounding Aseptic Isolator (CAI)
☐ Biological Safety Cabinet (BSC)
☐ Compounding Aseptic Containment Isolator (CACI)
☐ Integrated vertical clean bench
☐ Other: please describe _____

c. Where are your primary engineering controls located? (select all that apply)

☐ Positive Pressure ISO Class 7 buffer room with walls/doors
☐ Negative Pressure ISO Class 7 buffer room with walls/doors
☐ Positive Pressure ISO Class 7 anteroom
☐ Positive Pressure ISO Class 8 anteroom
☐ Non-ISO classed segregated compounding area for non-hazardous compounding
☐ Non-ISO classed containment segregated compounding room with 12 ACPH/negative pressure
☐ Other: please describe _____

d. What was the date of the last certification of your primary and secondary engineering controls?

_____

e. Did the certification of the primary and (if applicable) secondary engineering controls include testing of non-viable particle counts and airflow pattern smoke testing ***under dynamic operating conditions*** (while pharmacy staff are working or simulating work in the area being tested)?

☐ Yes ☐ No

2. What kind of gloves and alcohol are in use at your pharmacy for sterile compounding activities?

Describe briefly:

3. If your pharmacy uses isolators (Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators), describe how gloves are donned before compounding in your isolator(s).

☐ Not applicable because we do not use isolators for sterile compounding.

Describe briefly:

4. Primary engineering controls must be disinfected at frequent intervals with sterile 70% IPA during use but they also must be part of the daily cleaning routine. Briefly describe how the inside of your primary engineering controls are cleaned and disinfected (as well as the agents used) during your pharmacy's daily cleaning routine.

Describe briefly:

5. Before pharmacy staff or outsourced cleaning staff are allowed to perform daily and monthly cleaning activities, they must receive (at a minimum) training and competency verification in which two areas?

1.
2.

6. USP Chapter 797 requires that each compounding staff member successfully complete some training and testing before they are allowed to make compounded sterile preparations for human use. Briefly describe this type of training and testing at your facility.

Describe briefly:

7. These questions relate to viable air sampling. Please provide a short answer to each.

a. How often does your pharmacy perform viable air sampling? _____

b. Where is viable air sampling performed?_____

_____

c. How large are the samples of air you are sampling?_____

d. What are your action levels?_____

8. Surface sampling is an environmental metric that is required "periodically" by USP Chapter 797. How is it performed at your pharmacy? Briefly describe under what conditions it is performed, how often, with what and where it is performed.

Describe briefly:

9. USP Chapter 797 requires gloved fingertip sampling. Briefly describe how and when your pharmacy performs gloved fingertip sampling.

Describe briefly:

10. What activities would occur at your pharmacy if the results (number of colony forming units) of one of your environmental sampling samples exceeded the preselected Action Levels for that area.

Describe briefly:

11. Please explain how the concept of "first air" is critical to executing sterile compounding with proper aseptic technique.

Describe briefly:

12. If a pharmacy uses a 0.22 micron filter for the purposes of sterilization, what test is required before that batch may be released?

13. According to USP Chapter 797, is sterility testing required if a beyond-use date of 30 days refrigerated is assigned to a medium risk level batch?

Answer Yes or No and then briefly explain your rationale:

14. During a compounding process, the pharmacy removes the vial stopper from a product purchased from an FDA registered manufacturer. Does this change the risk level that should be assigned to the final compounded sterile product (CSP) made from that product and what risk level would you assign it?

Answer: Yes or No then indicate the risk level you would assign this CSP and your rationale:

15. Please describe your use of lyophilization in your pharmacy.

16. If a pharmacy has performed sterility testing on a batch (or outsourced it to a vendor who performs sterility testing in compliance with USP Chapter 71 on their behalf) and the batch fails, is it acceptable practice to retest that batch?

Answer Yes or No and then briefly describe your rationale:

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 | Tallahassee, FL 32314
(850) 245-4292 | www.floridaspharmacy.gov

NONRESIDENT STERILE COMPOUNDING APPLICATION FOR NONRESIDENT PHARMACIES

Please submit the application fee and unlicensed activity fee totaling $255 with your application.

_____Existing Nonresident Pharmacy Permit Number (If you do not have this permit, you must also submit an application for a Nonresident Pharmacy Registration.)

_____Existing Nonresident Sterile Compounding Permit Number (if applicable)

Federal Employer Identification Number (FEIN)

1. Corporate Name | **Telephone Number**

2. Doing Business As (d/b/a) | **E-Mail Address (Optional)**

3. Mailing Address

City | State | Zip

4. Physical Address

City | State | Zip

5. Prescription Department Manager (PDM) or Pharmacist In Charge (PIC) or equivalent

Name | License No. | Start Date

6. Contact Person | **Telephone Number**

7. DEA Registration Number (If applicable)

8. Do you have 24-hour access to patient records? ___Yes ____No
(If no, please provide an explanation on a separate sheet of paper)

9. Date of last inspection: Day _____ Month _____Year ____

Inspecting Authority_____

10. Was this inspection structured to ensure compliance with Chapters 797, 71, 85, and 731 of the United States Pharmacopeia? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).

_____Yes _____No

11. Prescription Department Operating Hours

Monday-Friday: Open _____Close: _____

Saturday: Open _____Close: _____

Sunday: Open _____Close: _____

12. Toll-Free Telephone Number
(available 6 days a week for 40 hours)

(_____) _____- _____

13. Ownership Information

a. Type of Ownership

_____Individual _____Corporation _____Partnership _____Other:_____

CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.

b. List each principal, officer, agent, managing employee or affiliated person of the applicant.

Attach a separate sheet if necessary.

Name/Title	Date of Birth	Mailing Address, City State, Zip Code	% Ownership
	/ /		%
	/ /		%
	/ /		%

Questions 14 through 18 are required pursuant to Section 456.0635(2), *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes or a similar felony offense committed in another state or jurisdiction? (If "no", skip to question 15.)

Yes_____ No _____

If "yes", for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction.

Yes_____ No_____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?

Yes_____ No _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", skip to question 16.)

Yes_____ No _____ (If yes, explain on a separate sheet providing accurate details)

If *"yes"*, is the date of application more than 15 years after the sentence and any subsequent period of probation ended?

Yes_____ No_____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? ? (If no, skip to question 16.)

Yes _____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If "no", skip to question 18)

Yes _____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No _____

If "yes", did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____

18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes_____ No_____

19. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes _____ No _____

State	Permit Type	Permit Number

20. Has the applicant or any principal, officer, agent, managing employee, or affiliated person ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy.

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

21. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

22. Has any principal, officer, agent, managing employee, affiliated person of the applicant ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (Include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

23. Is there any other permit issued by the Department of Health located at the physical location address on this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

24. Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have any outstanding fines, liens or overpayments assessed by a final order of the department?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

***If "yes",* does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have a repayment plan approved by the department?**

Yes _____ No _____

25. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 3 years?

Yes_____ No_____ (If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.)

APPLICANT SIGNATURE PAGE

Florida law requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application that takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department of board.

****

I, the undersigned, certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

I, the undersigned, hereby acknowledge that proving false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections 456.067, 465.015 (5), 775.082, 775.083, and 775.084, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true

SIGNATURE _____ TITLE _____DATE_____
Owner/Officer

****

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.floridaspharmacy.gov

ATTESTATION

Section 465.0158(3)(c), F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager (PDM) or Pharmacist In Charge (PIC).

I hereby attest and affirm that I have read and understand the laws and rules governing sterile compounding in the State of Florida, and that any sterile compounded product shipped, mailed, delivered, or dispensed into the State of Florida from our facility meets or exceeds the standards for sterile compounding set by the State of Florida and has not been compounded in violation of the laws and rules of the state, territory, or district in which our facility is located.

I declare that I have read the foregoing Attestation and that the facts stated in it are true.

SIGNATURE _____ TITLE _____DATE_____
(Owner/Officer)

SIGNATURE _____ TITLE _____DATE_____
(PDM/PIC)

Notice of Proposed Rule

DEPARTMENT OF HEALTH
Board of Pharmacy
RULE NO.: RULE TITLE:
64B16-32.009 Nonresident Sterile Compounding Permit for an Outsourcing Facility.
PURPOSE AND EFFECT: The Board proposes the rule promulgation to create a rule regarding nonresident sterile compounding permit for an outsourcing facility and to incorporate the Nonresident Sterile Compounding Permit Application for Outsourcing Facilities.
SUMMARY: A rule will be created regarding nonresident sterile compounding permit for an outsourcing facility and to incorporate the Nonresident Sterile Compounding Permit Application for Outsourcing Facilities.
SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.
The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.
Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.
RULEMAKING AUTHORITY: 465.0158 FS.
LAW IMPLEMENTED: 465.0158, 456.065(3) FS.
IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.
THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Allison Dudley, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254

THE FULL TEXT OF THE PROPOSED RULE IS:

64B5-32.009 Nonresident Sterile Compounding Permit for an Outsourcing Facility.
This permit is required before an outsourcing facility that is located outside of Florida, ships, mails, delivers, or dispenses, in any manner a compounded sterile product into Florida.

(1) An outsourcing facility that obtains a nonresident sterile compounding permit may ship, mail, or deliver a sterile compounded product into Florida for office-use and may ship, mail, deliver, or dispense a patient-specific compounded sterile product into Florida. This permit does not authorize the shipping, mailing, delivering, or dispensing of a non-compounded medicinal drug into Florida.

(2) A permit issued pursuant to this section shall be issued with the following conspicuously displayed on the front of the license: Outsourcing Facility Nonresident Sterile Compounding Permit – Patient Specific Prescription Compounding and Office-Use Compounding.

(3) An outsourcing facility applicant seeking a nonresident sterile compounding permit shall submit an application using Form DH5004-MQA (eff. 04/16), "Nonresident Sterile Compounding Permit Application for Outsourcing Facilities" which is hereby incorporated by reference. This Form is available at http://www.flrules.org/Gateway/reference.asp?No=Ref- or http://floridaspharmacy.gov.
Rulemaking Authority 456.0158, FS. Law Implemented 465.0158, 456.065(3) FS. History New _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 5, 2016

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 9, 2016

DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR OUTSOURCING FACILITIES

JULY 2016

DH5004-MQA, 07/16
Rule 64B16-32.009, F.A.C.

Nonresident Sterile Compounding Permit for Nonresident Pharmacies Information

A Nonresident Sterile Compounding Permit as authorized by Section 465.0158, *Florida Statutes* is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

Definitions:

a. For purposes of this application, when the term "affiliated person" is used, the term shall mean any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy.

b. For the purposes of this application, the term "supervising pharmacist" shall be the equivalent to the terms "prescription department manager" or "pharmacist in charge".

Application Processing

1. Please mail the application and the $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6330
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

2. Along with the application, Outsourcing Facilities must submit the following:

a. Proof of registration as an outsourcing facility with the Secretary of the U.S. Department of Health and Human Services.

b. A letter of licensure verification for the Prescription Department Manager or Pharmacist in Charge or equivalent (ie. supervising pharmacist) from the state, territory or district regulatory or licensing agency. The letter must include the original licensure date, the expiration date, and current licensure status.

c. A copy of a current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report is current if the inspection was conducted within six months before the date of submission of this application. The current inspection report must demonstrate that applicant is fully compliant with Current Good Manufacturing Practices that are adopted in Rule 64B16-27.797(3), Florida Administrative Code.

If you are unable to submit a current inspection report demonstrating compliance with Current Good Manufacturing Practices, due to acceptable circumstances as established by Rule 64B16-28.905, F.A.C. or if no current inspection has been performed, the applicant may:

- Submit a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act.
- Submit a current and satisfactory inspection report from an entity approved by the board. Approved entities can be found on the Board's website at www.floridaspharmacy.gov; or
- Request the Department to perform an onsite inspection in which all costs are borne by the applicant.

d. A copy of the applicant's existing policies and procedures for sterile compounding**.** The policies and procedures must comply with the standards for Current Good Manufacturing Practices.

e. Any and all other documentation requested or mandated within this application**.**

3. Once an application is complete and approved, board staff will issue a permit which you will received within 7 days of the issue date.

FLORIDA BOARD OF PHARMACY
P.O. Box 6330 | Tallahassee, FL 32314
(850) 245-4292 | www.floridaspharmacy.gov

NONRESIDENT STERILE COMPOUNDING APPLICATION FOR OUTSOURCING FACILITIES

Please submit the application fee and unlicensed activity fee totaling $255 with your application.

Federal Employer Identification Number (FEIN)

1. Corporate and Registered Outsourcing Facility Name | **Telephone Number**

2. Doing Business As (d/b/a) | **E-Mail Address (Optional)**

3. Mailing Address

City | State | Zip

4. Physical Address

City | State | Zip

5. Supervising Pharmacist

Name | License No. | Start Date

6. Contact Person | **Telephone Number**

7. DEA Registration Number (If applicable)

8. Do you have 24-hour access to patient records for those patients who receive a dispensed compounded product pursuant to a patient specific prescription.
___Yes ____No (If no, please provide an explanation on a separate sheet of paper)
____N/A Do not engage in patient specific compounding

9. Date of last inspection: Day _____ Month _____Year _____

Inspecting Authority_____

10. Was this inspection structured to ensure compliance with Current Good Manufacturing Practices? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).

_____Yes _____No

11. If you are engaging in patient specific sterile compounding, please provide a toll-free telephone number that is available 6 days a week for 40 hours.

(_____) _____- _____

12. Ownership Information

a. Type of Ownership

_____Individual _____Corporation _____Partnership _____Other:_____

CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.

b. List each principal, officer, agent, managing employee or affiliated person of the applicant.

Attach a separate sheet if necessary.

Name/Title	Date of Birth	Mailing Address, City State, Zip Code	% Ownership
	/ /		%
	/ /		%
	/ /		%

Questions 13 through 17 are required pursuant to Section 456.0635(2), *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.

13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes or a similar felony offense committed in another state or jurisdiction? (If no, skip to question 14.)

Yes_____ No _____

If "yes", for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction.

Yes_____ No_____

If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?

Yes_____ No _____

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", skip to question 15.)

Yes_____ No _____ (If yes, explain on a separate sheet providing accurate details)

If *"yes"*, is the date of application more than 15 years after the sentence and any subsequent period of probation ended?

Yes_____ No_____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? ? (If "no", skip to question 16.)

Yes _____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If "no", skip to question 17)

Yes _____ No _____

If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No _____

If "yes", did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____

17. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes_____ No_____

18. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes _____ No _____

State	Permit Type	Permit Number

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy.

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

20. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

21. Has any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (Include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

22. Is there any other permit issued by the Department of Health located at the physical location address on this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

23. Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have any outstanding fines, liens or overpayments assessed by a final order of the department?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

If "yes" to 26: **Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have a repayment plan approved by the department?**

Yes _____ No _____

24. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 5 years?

Yes_____ No_____ (If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.)

APPLICANT SIGNATURE PAGE

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****

I, the undersigned, certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit.

I, the undersigned, hereby acknowledge that proving false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections 456.067, 465.015 (5), 775.082, 775.083, and 775.084, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true

SIGNATURE _____ TITLE _____DATE_____
Owner/Officer

****

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ATTESTATION

Section 465.0158(3) (c), F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's supervising pharmacist.

I hereby attest and affirm that I have read and understand the laws and rules governing sterile compounding in the State of Florida, and that any sterile compounded product shipped, mailed, delivered, or dispensed into the State of Florida from our facility meets or exceeds the standards for sterile compounding set by the State of Florida and has not been compounded in violation of the laws and rules of the state, territory, or district in which our facility is located.

I declare that I have read the foregoing attestation and that the facts stated in it are true.

SIGNATURE _____ TITLE _____DATE_____
(Owner/Officer)

SIGNATURE _____ TITLE _____DATE_____
(Supervising Pharmacist)